Patient Information Leaflet

SCHEDULING STATUS

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POVIDONE IODINE SCRUB B. BRAUN

(Povidone Iodine)

(Liquid)

Read all of this leaflet carefully before you start using POVIDONE IODINE SCRUB B. BRAUN is available without a doctors prescription for you. Nevertheless, you still need to use POVIDONE IODINE SCRUB B. BRAUN carefully to get the best results.

- Keep this leaflet. You may need to read it again.
- Do not share POVIDONE IODINE SCRUB B. BRAUN with any other person
- Ask your health care provider or pharmacist if you need more information or advise.

What is in this leaflet:

1. What POVIDONE IODINE SCRUB B. BRAUN is and what it is used for
2. What you need to know before you use POVIDONE IODINE SCRUB B. BRAUN
3. How to use POVIDONE IODINE SCRUB B. BRAUN
4. Possible side effects
5. How to store POVIDONE IODINE SCRUB B. BRAUN
6. Contents of the pack and other information

1. What POVIDONE IODINE SCRUB B. BRAUN is and what it is used for

POVIDONE IODINE SCRUB B. BRAUN is a surgical scrub used for the degerming of the hands prior to surgical procedures and pre-operative preparation of the patient's skin. POVIDONE IODINE SCRUB B. BRAUN may be used to advantage on the patient's skin following the use of the scrub.

Effective as an antiseptic wash in infected skin conditions and a general germicidal (germs) cleanser in consulting rooms.

2. What you need to know before you use POVIDONE IODINE SCRUB B. BRAUN

Do not use POVIDONE IODINE SCRUB B. BRAUN:

- If you are allergic (hypersensitive) to povidone iodine or any of the ingredients POVIDONE IODINE SCRUB B. BRAUN listed in section 6,
- On children younger than 2 years of age,
- History of abnormal thyroid function or goitre (in particular nodular colloid goitre, endemic goitre and Hashimoto's thyroiditis),
- Regular use should be avoided in patients on concurrent lithium therapy.

Warnings and precautions

Tell your doctor before being administered the product

- If you are allergic to iodine
- If you are doing regular thyroid tests, regular use of this preparation may interfere with these tests
- If you have burns and scars as the iodine content seeps through these at some level, in particular if you suffer from renal insufficiency
- Severe metabolic acidosis (a condition in which too much acid accumulates in the body) may occur in patients suffering from burns greater than 20 % of the body surface
- It may permanently discolour white gold jewellery and it is recommended that his type of jewellery be removed before using POVIDONE IODINE SCRUB B. BRAUN.

Other medicines and POVIDONE IODINE SCRUB B. BRAUN:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

If you are using any of the following you should notify your doctor before receiving POVIDONE IODINE SCRUB B. BRAUN.

- Use with lithium therapy, as this shows signs of hypothyroidic effects (decrease in thyroid levels). Absorption of iodine from povidone iodine through either intact skin or broken skin may interfere with thyroid function tests.
- Contamination with iodine with several types of occult blood in in faces or blood in urine may produce false positive results.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before using POVIDONE IODINE SCRUB B. BRAUN.

Iodine crosses freely through the placenta and it is secreted into the breast milk. Which can cause thyroid function disorders in the offspring.

3. How to use POVIDONE IODINE SCRUB B. BRAUN

Use POVIDONE IODINE SCRUB B. BRAUN exactly as described on the leaflet or as your doctor, pharmacist or nurse told you. Check with your doctor, pharmacist, or nurse if you are not sure.

POVIDONE IODINE SCRUB B. BRAUN should be used undiluted.

Must NOT be used on children under 2 years if age.

If you take POVIDONE IODINE SCRUB B. BRAUN:

The symptoms of an overdosage from acute poisoning are from ingestion of the iodine and this is mainly due to the corrosive effects on the gastro-intestinal tract (the gut). The signs are:

- A disagreeable metallic taste
- Vomiting

- Stomach pain
- Diarrhoea

If the stomach contains starch the vomit colour will be blue.

Anuria (failure of the kidneys to produce urine) may occur 1-3 days later. Death may be due to circulatory failure, oedema (build-up of fluid in the body which causes the affected tissue to become swollen) of the glottis (part of the throat) resulting in asphyxia or pulmonary oedema (heart attack).

4. Possible side effects

POVIDONE IODINE SCRUB B. BRAUN can cause side effects.

Not all side effects reported for POVIDONE IODINE SCRUB B. BRAUN are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving POVIDONE IODINE SCRUB B. BRAUN, please consult your health care provider for advice.

If any of the following happens, stop receiving POVIDONE IODINE SCRUB B. BRAUN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Local irritations, skin burns and skin sensitive reactions
- Anaphylactic and anaphylactoid reactions (life threatening allergic reaction)
- Anaphylactic shock (immune system releases a number of chemicals that can cause you to go into shock)
- Excess iodine usage can produce goitre (a large sweeling of the neck, thyroid gland)

These are all very serious side effects. If you have them, you may have a serious reaction to POVIDONE IODINE SCRUB B. BRAUN**.** You may need urgent medical attention or hospitalisation.

- Hypothyroidism (abnormally low activity of the thyroid gland)
- Hyperthyroidism (abnormally high activity of the thyroid gland)
- Metabolic acidosis (A condition in which too much acid accumulates in the body)
- Acute renal failure (A condition in which the kidneys suddenly can't filter waste from the

blood)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects. Talk to your doctor, or pharmacist or nurse. You can also report side effects to SAHPRA via "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/index/8.

By reporting side effects, you can help provide more information on the safety of POVIDONE IODINE B. BRAUN.

5. How to store POVIDONE IODINE SCRUB B. BRAUN

Store all medicines out of reach of children

Store at or below 25ºC.

Store in airtight containers.

Store in cool dry place.

Protect from light.

6. Contents of the pack and other information

What POVIDONE IODINE SCRUB B. BRAUN contains

The active ingredient is povidone iodine. Each 100 mL of POVIDONE IODINE SCRUB B. BRAUN contains 7,5 g of Povidone Iodine equal to 0.75 g of available iodine.

Other ingredients:

Trisodium phosphate

Citric Acid

Glycerine

Hydroxyethylcellulose (Natrasol)

SLES (Sodium Laureth Sulphate)

Purified Water

What POVIDONE IODINE SCRUB B. BRAUN looks like and contents of the pack

POVIDONE IODINE SCRUB B. BRAUN is a deep brown coloured foaming liquid having the characteristic odour of iodine.

POVIDONE IODINE SCRUB B. BRAUN comes in HDPE plastic containers, 50 mL, 500 mL with cap, 500 mL with pump and 1L with cap.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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